

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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AMERICAN ACADEMY OF PEDIATRICS,  
MASSACHUSETTS CHAPTER OF AMERICAN  
ACADEMY OF PEDIATRICS, INC.,  
AMERICAN CANCER SOCIETY, INC.,  
AMERICAN CANCER SOCIETY CANCER  
ACTION NETWORK, INC., AMERICAN  
HEART ASSOCIATION, INC., AMERICAN  
LUNG ASSOCIATION, CAMPAIGN FOR  
TOBACCO-FREE KIDS, TRUTH INITIATIVE  
FOUNDATION D/B/A TRUTH INITIATIVE,  
DR. TED KREMER, DR. JONATHAN  
WINICKOFF and DR. LYNDA YOUNG,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG  
ADMINISTRATION

Defendant.

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Civil Action No. 16-cv-11985 (IT)

**DEFENDANT’S SUPPLEMENTAL FILING**

At oral argument on January 24, 2018, Plaintiffs argued that provisions of the Paperwork Reduction Act (“PRA”), 44 U.S.C. §§ 3501-3521, and Executive Order (“EO”) 12866 (“Regulatory Planning and Review”), § 6(a)(3)(D), 3 C.F.R. 638 (1994), 58 Fed. Reg. 51735, 51741 (Oct. 4, 1993),<sup>1</sup> allow an agency to seek the Office of Management and Budget’s (“OMB’s”) expedited review and approval of (1) research involving information collections and (2) proposed and final rules. Per the Court’s request, Defendant submits the following response.

**1. OMB Review of Proposed Collections of Information by Federal Agencies**

Under the PRA, federal agencies generally must provide notice and opportunity for public comment and obtain OMB approval before collecting information from 10 or more

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<sup>1</sup> After the hearing, Plaintiffs identified the specific EO provision on which they rely.

persons. 44 U.S.C. §§ 3502(3)(A)(i); 3506(c), 3507(a). Research that involves such information collection is subject to the requirements of the PRA. *See* 5 C.F.R. § 1320.3(c) (defining “collection of information”). Before seeking OMB approval to conduct such research, an agency typically must first publish a 60-day notice in the Federal Register allowing for public comment on its proposed collection of information. 44 U.S.C. § 3506(c)(2)(A). After reviewing public comments, the agency submits its information collection request (“ICR”) to OMB and publishes a 30-day notice allowing for public comment to OMB on the ICR. 44 U.S.C. § 3507(b); 5 C.F.R. § 1320.10(a).

OMB review of an ICR often involves questions, comments, and revisions to the proposed information collection. If OMB approves an ICR, it assigns a control number and an expiration date for the authorization; it may authorize collections of information for no more than 3 years. 44 U.S.C. § 3507(a)(3); 5 C.F.R. § 1320.10(b). An agency must include the control number in every information collection and must also disclose that an agency may not conduct or sponsor—and a person is not required to respond to—a collection of information unless it displays a valid control number. 44 U.S.C. § 3506(c)(1)(B)(i), (B)(iii)(V); *see also Dole v. United Steelworkers*, 494 U.S. 26, 40 (1980) (if OMB does not issue a control number, “the agency is prohibited from collecting the information”).

## **2. Mechanisms for Expedited OMB Approval of Collections of Information under the PRA and Review of Rulemaking under EO 12866**

### **A. 60-Day Non-Response Mechanism under the PRA**

The PRA requires OMB to respond to an agency’s ICR within 60 days, 44 U.S.C. § 3507(c)(2), and describes a 60-day non-response mechanism. *Id.* § 3507(c)(3). “If OMB fails to notify the agency of its approval, instruction to make substantive or material change, or disapproval within the 60-day period, the agency may request, and OMB shall assign without

further delay, an OMB control number that shall be valid for not more than one year.” 5 C.F.R. § 1320.10(c).

After diligent research and consultation with knowledgeable government personnel, undersigned counsel are aware of no prior instance where this provision has been invoked by any agency.

### **B. Emergency Review Provision under the PRA**

A separate provision of the PRA allows for expedited or emergency review of an ICR. In certain circumstances, an “agency head” may ask OMB to authorize an information collection within a time that the agency specifies. 44 U.S.C. § 3507(j)(1)-(2). The agency head must determine that the collection is needed “prior to” the expiration of time periods provided under the PRA and is “essential to the mission of the agency,” and either that “an unanticipated event has occurred,” or that normal clearance procedures are “reasonably likely” to result in “public harm,” “prevent or disrupt the collection of information,” or “cause a statutory or court ordered deadline to be missed.” *Id.* § 3507(j)(1)(A)(i)-(ii), (j)(1)(B).

OMB has stated that approval of a request for an emergency review “depends on a number of factors including, but not limited to, the imminence and likelihood of the stated public harm; the unforeseeability of the event or statutory or court-ordered deadline; and the necessity of the information collection to the mission of the agency.” OMB Memorandum, “Facilitating Research by Streamlining the Paperwork Reduction Act Process,” p.7 (Dec. 9, 2010), <http://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2011/m11-07.pdf>. Situational examples include “public health epidemic,” “natural disaster, serious accident, or economic crisis,” and the missing of a “statutory or court-ordered deadline.” *Id.* OMB has also stated that it “may modify—or, if necessary, waive—the public comment requirements” when determining a

“suitably streamlined process” for expedited review. OMB Memorandum, “Flexibilities under the Paperwork Reduction Act for Compliance with Information Collection Requirements,” p.5 (July 22, 2016), [https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/inforeg/inforeg/pra\\_flexibilities\\_memo\\_7\\_22\\_16\\_final.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/inforeg/inforeg/pra_flexibilities_memo_7_22_16_final.pdf). The statute provides that information collections approved under the emergency review provision may be conducted only for a maximum of 180 days. 44 U.S.C. § 3507(j)(2).

### **C. OMB Review of Rulemaking under EO 12866**

Distinct from its review of proposed collections of information under the PRA, OMB reviews “significant regulatory actions,” such as proposed and final rules, under EO 12866. Exec. Order No. 12866, §§ 3(e)-(f), 6(b)(i). Plaintiffs have asserted that § 6(a)(3)(D) authorizes expedited emergency review of rules. That section does not appear to accelerate OMB review time. It states that agencies are required to notify OMB of “emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow.” For “regulatory actions that are governed by a statutory or court-imposed deadline,” the EO requires agencies, “to the extent practicable,” to “schedule rulemaking proceedings so as to permit sufficient time for [OMB] to conduct its review.” *Id.* The EO provides no further requirements or guidance regarding agency or OMB responsibilities for emergency rulemaking situations.

### **3. Defendant’s Previously Pending ICRs**

Defendant previously notified the Court that two of its research studies had been delayed due to the pendency of approval of the related ICRs by OMB (ECF No. 42; filed 1/22/2018). On January 29, 2018, OMB approved both ICRs. Information collection for the quantitative study on wording began on January 30, 2018; recruitment of focus group participants for the final qualitative study on images will begin by February 6, 2018.

Dated: February 1, 2018

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as nonregistered participants on today's date.

/s/ Daniel K. Crane-Hirsch  
February 1, 2018